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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,955	08/27/2001	Chad C. Steele	BC-0112-P04	7282

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GAMBRO, INC  
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EXAMINER

BIANCO, PATRICIA

ART UNIT PAPER NUMBER

3762

DATE MAILED: 07/16/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/940,955

Applicant(s)

STEELE ET AL.

Examiner

Patricia M Bianco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-20 and 24-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☒ Other: *Detailed Action*.

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election with traverse of Group II, claims 21-23, in Paper No. 4 is acknowledged. Applicant's traversal is on the ground(s) that Applicant believes both group I and group II are directed to the same invention, that being a method of processing blood in an apheresis system and further are related to the presence of a first condition. Applicant further argues that a single search and examination would not be burdensome. Applicant then requested the withdrawal of the restriction requirement and the examination of the claims of both groups I and II. This argument is not found persuasive because as stated in M. P. E. P. § 803, for purposes of initial requirement, a serious burden on the Examiner may be *prima facie* shown "by appropriate explanation either separate classification, separate status in the art, or a different field of search." That *prima facie* showing may be rebutted by appropriate showings or evidence by the Applicant. It is the position of the Examiner that a proper restriction was set forth since the different classification of the two inventions meets the requirements for setting forth a restriction since the method of group I is an automated process or method for determining a condition(s) and the method of group II requires an operator to perform the function. Therefore, the two methods are sent to be distinct inventions. It is a burden on the Examiner insofar as searching in different classes for the distinct inventions. See 37 CFR 1.111.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-20 and 24-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 4.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### ***Information Disclosure Statement***

Applicant filed a copy of a Notice of References Cited (PTO-892) from parent case 09/012,672 cited by Examiner Noggle as part of the Information Disclosure Statement filed 12/18/01. It is not a proper to submit a copy of the PTO-892 as part of the IDS. However, the references have been considered and cited on a new PTO-892 as part of the instant application.

The information disclosure statement filed 12/18/01 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the

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information referred to therein has not been considered. Although applicant stated that the references cited on the IDS were in applications 08/483515, & 08/959534, 09/012672, upon review of the file not all the references were in the files. The examiner has considered the US Patents and PCT documents at this time. However, the European patents (documents ADD, AEE, AHH), the UK patent (AFF), the German patent (AKK), document ALL (country is illegible on fax copy) and the other art cited (documents AMM-AWW & BA-BM) have not been considered.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lyle et al. (5,956,023). Lyle et al. (hereafter Lyle) teaches of medical processing device having a control system that can be operator controlled or automatic, depending on preference. The medical device is a separation system 10 for processing whole blood into its components (i.e. apheresis) includes a centrifuge 12, a disposable fluid processing assembly (i.e. at least one blood passageway), a pressure monitor (i.e. a sensor) and a controller 18 for presiding over the system and its operation. The system controller monitors the functions and overall processes control of the blood separation system and its components via a main processing unit (MPU). The MPU employs a microprocessor

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that allows for real-time monitoring and tasking including a timer for preempting the steps carried out in the process. The MPU is in communication to receive input and deliver output to the main parts of the system, such as the centrifuge, pumps, tubing, sensor etc.. The MPU may have an interactive operator interface for the operator to view, comprehend, troubleshoot and change the function and performance of the system. The display may be in alphanumeric or graphical images along with a voice prompt to instruct the operator to take action. The MPU has a status region that continuously shows prescribed procedure-dependent information and general information to keep the operator apprised of the status of the process. The operator may use the working region of the MPU to monitor and change aspects of the ongoing process. The operator may use the interface of the MPU to find and select any of detailed procedures, functions and options of the system. The operator may perform these functions using touch activation. Lyle discloses the invention substantially as claimed, however, fails to disclose specifically that the operator performs the steps of first prompting of a condition that is a problem relating to the method and second prompting the apheresis system to perform a remedial action. As Lyle discloses, the operator may check the status and/or working regions for the prescribed procedure-dependent information and general information and further teaches that the operator may use the working region of the MPU to monitor and change any aspects of the ongoing process. It is the position of the examiner that during this monitoring, any of the information in the stored procedure may need to be changed to account for changes in the patient during the ongoing procedure. These changes are seen to be equivalent

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to the claimed problem relating to the method and the operator would change the prescribed procedure using the MPU, thereby performing the second prompting or remedial step.

***Conclusion***

Any inquiry concerning the rejections contained within this communication or earlier communications from the examiner should be directed to Patricia M. Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday-Friday, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communications and (703) 306-4520 for After Final communications.

pmb

July 12<sup>th</sup>, 2003

